PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

GILSON et al.

Docket No: A8937

Appln. No.: 10/058,828

Group Art Unit: 3731

Confirmation No.: 3776

Examiner: Uyen T. Ho

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For: EMBOLIC PROTECTION DEVICE

DECLARATION OF JOHN O'SHAUGHNESSY

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I John O'Shaughnessy, do declare and state as follows:

1. I am a citizen of the Republic of Ireland, and reside at Furrymelia - East, Barna, County Galway, Ireland.
2. This declaration is submitted in support of a request for interference with U.S. Patent Application Serial No. 09/723,003, filed November 27, 2000, pursuant to 37 C.F.R. §41.202(a).
3. During the events described herein, I was employed by MedNova as Executive Director and CEO of MedNova, and participated in meetings and conferences with the inventors and other employees concerning the design of the embolic filter system, and their responsibilities in its development.
4. During MedNova's development and design of embolic filter protection systems, I worked closely with Paul Gilson, Eamon Brady, Padraig Maher, David Vale, and Chas Taylor (referred to herein collectively as "the inventors"), and regularly participated in meetings and conferences

concerning the design of the embolic filter system. I am familiar with their work and with the work of other MedNova researchers and engineers in developing this product.

I. BACKGROUND

5. At the time of the events described herein, MedNova was a start-up company located in Galway, Ireland.

6. During the events described herein, Paul Gilson was employed by MedNova as Executive Director and Chief Scientific Officer. During this period, Paul Gilson was responsible for Operations, Research and Development, Regulatory Affairs and Quality Control.

7. During the events described herein, Eamon Brady was engaged by MedNova as Research and Development Manager. During this period, Eamon Brady was responsible for MedNova's embolic filter protection device development project.

8. During the events described herein, Padraig Maher was employed by MedNova as a Research and Development Engineer.

9. During the events described herein, David Vale was employed by MedNova as a Senior Development Engineer.

10. During the events described herein, Chas Taylor was employed by MedNova as Executive Director and Marketing Director. During this period, Chas Taylor's responsibilities at MedNova included clinical studies, marketing and sales.

11. At the time of the events described herein, MedNova's research and development activities were directed to two potential product lines, one of which was an embolic protection device. The embolic protection system

was MedNova's principal research and development project during the time of the events described herein.

12. Because MedNova was a small company, concentrating principally on development of embolic protection systems and methods for using them, I and other employees working on the embolic filter project worked closely with the inventors, on a daily basis, and was familiar with their basic concept and with the refinements and developments of the filter which led to the filing of Irish Patent Application 98 0267 on April 8, 1998. I worked especially closely with Paul Gilson with whom I shared an office in the relevant period.

13. I was familiar with the design and development of the embolic protection filter device, including the system for introducing, deploying, and removing the filter device from a vessel, and the methods for using the system contemplated by the inventors, from its inception and throughout its development.

14. I have read and understand the two counts which are proposed for the interference that are described herein.

Proposed Count 1 **(Gilson Claim 97)**
A method of filtering emboli from blood flowing through a vessel, the method comprising: providing a guide wire having a distal stop, and a filter element having a capture ring disposed for translation on the guide wire proximal of the stop; transluminally inserting the guide wire and filter element into a vessel; deploying the filter element to engage a wall of the vessel, the filter element filtering emboli out of blood flowing through the vessel;

advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element, rotation or distal translation of the guide wire relative to the filter element not displacing the filter element.

Proposed Count 2 (Gilson Claim 98)
A method of filtering emboli from blood flowing through a vessel, the method comprising: providing a guide wire having a distal region including a distal stop, and a filter element disposed for translation on the guide wire proximal to the distal stop, the filter element comprising a plurality of self-expanding struts having a filter sac affixed thereto; transluminally inserting the guide wire and filter element into a vessel; deploying the filter element so that the struts and filter sac expand to engage a wall of the vessel, the filter sac filtering emboli out of blood flowing through the vessel; advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element, rotation or distal translation of the guide wire relative to the filter element not displacing the filter element; further comprising retracting the guide wire in a proximal direction to cause the distal stop to abut against the filter element.

15. Subsequent to January 1, 1996, and prior to March 5, 1998, the inventors described to me each aspect of their invention defined by Count 1.

16. Subsequent to January 1, 1996, and prior to March 5, 1998, the inventors described to me each aspect of their invention defined by Count 2.

17. All events referred to herein occurred subsequent to January 1, 1996.

II. CONCEPTION

18. With regard to Count 1, prior to March 5, 1998, the inventors disclosed to me an embodiment of their invention that is disclosed in Irish Application No. 97 0789, filed on November 7, 1997, as described in the following table:

Disclosure of Irish Application No. 97 0789
A filter element provides a pathway for blood and has means for capturing and retaining undesired embolic material released during a surgical procedure (page 11, lines 19-24). The device is used in an over the wire transcatheter configuration, in which the clinician will cross the lesion with a steerable guidewire (page 12, lines 3-5). The device consists of a filter attached to a shaft that can run over the primary crossing guidewire (page 12, lines 11-13); the shaft is disposed for translation on the guide wire proximal of the distal end of the guidewire, for example, substrate shaft 33 in Figs. 11-15 and 18, which is threaded over a guidewire (page 16, lines 6-8). The clinician will cross the lesion with a steerable guidewire, and the filter is then threaded over the guidewire and placed distal to the site of the lesion being treated (page 12, lines 4-8). The filter is deployed into the vessel and will capture emboli (page 12, lines 8-11); the deployed filter element will occlude the vessel except for the path or paths provided through the filter (page 12, lines 21-24). The deployed filter is placed distal to the site of the lesion being treated and will capture emboli that are generated or dislodged during balloon inflation and stent placement, which are treatment devices advanced along the guide wire to a position proximal to the location of the filter (page 12, lines 4-11; page 19, lines 10-17; Claims 23, 24).

> Because the shaft or hollow support element (page 12, lines 14-18) on which the filter is mounted is not fixed to the guidewire (page 12, lines 11-13), rotation or distal translation of the guidewire relative to the filter element does not displace the filter element. The guidewire moves independently from the filter:
> it is first steered across the lesion, and the filter is then threaded over the inserted guidewire and deployed in the vessel (page 12, lines 3-11). During retrieval, the filter can be withdrawn either with the guidewire or over it (page 16, lines 23-25). The filter is attached to a shaft that can run over the prior crossing guidewire (page 12, lines 11-13), and rotation or distal translation of the guidewire relative to the shaft thus does not displace the filter element.

19. Prior to March 5, 1998, the inventors disclosed to me an embodiment of their invention that is disclosed in a drawing from David Vale's laboratory notebook which is attached as Exhibit 1. At the time that Exhibit 1 was made, I met frequently with the inventors to discuss the initial design of the embolic filter and system. The inventors disclosed to me, and I understood the filter protection system described in Exhibit 1 and the methods for its use during angioplasty and stenting procedures, prior to March 5, 1998. More particularly, I confirm that the inventors disclosed to me and I understood each of the following components and uses of the embolic filter protection system described in Exhibit 1, prior to March 5, 1998.

20. Exhibit 1 is an accurate description of an embodiment of an embolic protection system, called the "Neuroguard" system. Exhibit 1 is an illustration of the Neuroguard system as drawn by David Vale and as that embodiment existed prior to March 5, 1998. Exhibit 1 illustrates the details and dimensions of a delivery catheter having a Y-shaped Touhy Borst adapter and a catheter shaft of wound springwire having a Teflon® (*i.e.*, polytetrafluoroethylene or "PTFE") heat-shrink cover. The delivery

catheter is used to transluminally insert a filter element into a blood vessel, and to deploy the filter element in the blood vessel.

21. The filter element is described as a "Chronoflex"™, (*i.e.*, polyurethane which is used to form a membrane) balloon filter sac mounted on a polyimide tube support.

22. The polyimide tube has an outer diameter of 0.0179″ and an inner diameter of 0.0145″.

23. The "Chronoflex" balloon filter is illustrated in an expanded configuration, in which a "balloon" filter having a main body thickness of 0.002″ is attached by adhesive to the polyimide tube and to a Nitinol framework which supports the filter sac.

24. The balloon or membrane filter is shown with large orifices at the proximal end of the filter, which permit the entry of blood containing emboli, and with smaller orifices at the distal end of the filter, which filters emboli from blood flowing through the filter and out the smaller orifices.

25. Nitinol is a self-expanding material, and in the illustrated embodiment the self-expanding filter sac is shown in its deployed configuration, expanded by a supporting Nitinol framework which has four struts attached to a proximal ring which is adjacent to the larger filter openings at the proximal end of the filter.

26. Within the inner lumen of the polyimide tube, which has an inner diameter of 0.0145″, is optionally disposed a guidewire having a maximum shaft diameter of 0.014″ to allow for rotation and translation of the guidewire relative to the filter element.

27. I understood from the inventors at the time that Exhibit 1 was made, that the filter element is advanced over a guide wire, and that they considered it important that rotation or distal translation of the guide wire relative to the

filter element would not displace the deployed filter element. I also understood at that time that in the system described in Exhibit 1, the guidewire may be rotated or distally translated relative to the polyimide tube without displacing the filter mounted on the tube, because the inner diameter of the polyimide tube is larger than the diameter of the guidewire.

28. In Exhibit 1, the guidewire extends through the inner lumen of the filter element polyimide tube, and extends beyond the distal end of the filter, which is disposed near the distal end of the guidewire.

29. Exhibit 1 also refers to an interface of the filter element polyimide tube and treatment devices including a balloon catheter and a stent balloon catheter, which are indicated to have a minimum lumen interior diameter of 0.020".

30. As confirmed by Exhibit 1, the inventors disclosed to me that conventional treatment devices such as a balloon catheter and a stent balloon catheter may be advanced along the guidewire over the polyimide tube, which has an outer diameter of 0.0179".

31. With regard to Count 1, prior to March 5, 1998, the inventors disclosed to me the following aspects of their invention which are shown in Exhibit 1:

Neuroguard Details and Dims.
The CHRONOFLEX balloon filter is used in the method disclosed in Irish Application No. 97 0789, as shown, *e.g.*, in Fig. 18. Guidewire having a maximum shaft outer diameter (O.D.) of 0.014". The balloon filter is disposed on a polyimide tube having an inner diameter (I.D.) of 0.0145", and is thus disposed for translation on the guide wire proximal of the distal end of the guide wire. Exhibit 1 illustrates the filter polyimide tube support and guidewire extending from a delivery catheter that is transluminally inserted into a vessel, as described in Irish Application No. 97 0789.

The self-expanding CHRONOFLEX filter is shown in deployed configuration, as described in Irish Application No. 97 0789, to engage a wall of the vessel and filter emboli out of blood flowing through a vessel in which the filter is deployed.

Treatment devices such as a balloon catheter or a stent balloon catheter disclosed in Exhibit 1 are inserted into a vessel to treat a portion of the vessel, and are advanced along the guidewire to a position proximal of the filter element, as described in Irish Application No. 97 0789.

Because Exhibit 1 describes the inner lumen of the polyimide tube as having a diameter of 0.0145", and the guidewire has a maximum shaft outer diameter of 0.014", Exhibit 1 discloses that rotation or distal translation of the guide wire relative to the filter element does not displace the filter element.

32. Prior to March 5, 1998, the inventors disclosed to me their concept of a dual-diameter or "stepped" guidewire with a distal end region having a diameter greater than the proximal diameter, which permits the filter element to translate distally and rotate on the guidewire proximal of the thicker distal end, but prevents translation of the filter distal to the thicker distal end.

33. I understood at that time that in the filter element shown in Exhibit 1, the polyimide tube on which the balloon filter is mounted is designed to rotate and translate on the guidewire, because the guidewire has a smaller diameter (0.014") than the inner lumen of the polyimide tube (0.0145").

34. Prior to March 5, 1998, the inventors disclosed to me that a small clearance between the guidewire and the polyimide tube caused undesirable friction between the guidewire and the tube.

35. In a conference call design review meeting prior to March 5, 1998, Chas Taylor referred to a solution to this problem by using a custom guidewire,

having a thinner proximal portion on which the filter element polyimide tube support is mounted. He referred to a stepped guidewire having a proximal diameter of 0.012″ and a distal end diameter of 0.018″.

36. Prior to March 5, 1998, I received an email describing the conference call meeting which was attended by inventors Chas Taylor, Padraig Maher, David Vale and Eamon Brady, and also by John O'Shaughnessy, which is attached as Exhibit 3.

37. Prior to March 5, 1998, the inventors disclosed to me that a stepped guidewire, having a distal end portion with a diameter greater than the inner diameter of the polyimide tube (0.0145″) would serve as a distal stop, which limits distal translation of the filter on the guidewire.

38. Their appreciation of the distal stop function of the stepped guidewire is shown by a memorandum describing a meeting of Chas Taylor with a vascular radiologist, Peter Gaines, that took place prior to March 5, 1998, attached as Exhibit 5). Exhibit 5 describes a question from Dr. Gaines, asking how to remove the guidewire if the tip of the guidewire needs to be reformed, to permit better steering of the guidewire in the vessel if there is any difficulty in passing the lesion after the guidewire and filter are inserted in the vessel. The document states that because of the stepped guidewire configuration, the guidewire cannot be removed from the polyimide support of the filter element when in place in a vessel. Chas Taylor indicated that the best solution was to remove both the filter and guidewire from the vessel, to reform the guidewire outside the vessel, and to transluminally reinsert both the guide wire and the filter into the vessel through the guiding catheter.

39. A copy of this memorandum was provided prior to March 5, 1998, to the inventors and to me.

40. Prior to March 5, 1998, the inventors disclosed to me that because of the stepped guidewire configuration, the guidewire can not be removed proximally through the polyimide support of the filter element. It is necessary to backload the stepped guidewire through the filter support in order to prepare the filter system for use.

41. Prior to March 5, 1998, the inventors disclosed to me that they considered that the optimal stepped guidewire configuration for use with a polyimide tube filter support having an inner diameter of 0.0145" was a custom guidewire having a proximal diameter of 0.013", which would permit rotation and distal translation of the filter on the proximal portion of the guidewire, and a distal end diameter of 0.016", which would act as a distal stop.

42. Paul Gilson placed an order for the custom stepped 0.013"/0.016" guidewire was placed with a guidewire manufacturer, Lake Region Manufacturing Co., prior to March 5, 1998. This order is confirmed by a facsimile from Tom Kleist of Lake Region, dated prior to March 5, 1998, and an invoice from Lake Region, showing that the custom stepped 0.013"/0.016" guidewire was shipped to MedNova and received prior to March 5, 1998 (Exhibit 7).

43. Prior to March 5, 1998, MedNova used this custom 0.013"/0.016" guidewire in prototype filter systems including the "Mark 1 NeuroShield" filter system as shown in Exhibit 90.

44. Prior to March 5, 1998, the inventors and other MedNova employees constructed an embodiment of a prototype filter device and system which was designated as the "NeuroShield Mark 1" embolic filter protection system. I am familiar with the construction of this prototype, which was designed to be used in the method described in Irish Application 97 0789.

A true and accurate photograph of a filter element of a NeuroShield Mark 1 embolic filter protection system prototype is attached as Exhibit 90.

45. With regard to Count 1, prior to March 5, 1998, I understood that the prototype NeuroShield Mark 1 filter system included the following features of the invention:

NeuroShield Mark 1 Prototype (Exhibit 90)
The filter system is used in the method disclosed in Irish Application No. 97 0789, where a representative filter is shown, *e.g.*, in Fig. 18. The balloon filter shown in Exhibit 90 is mounted on a polyimide tube support having an inner diameter of 0.0145", and the filter is disposed for translation on the guide wire proximal of the distal stop of the guide wire. The polyimide tube support prevents the filter from translating distal of the guidewire stop. Exhibit 90, shows the filter polyimide tube support. The balloon filter is shown in Exhibit 90, in its deployed configuration, as described in Irish Application No. 97 0789, to engage a wall of the vessel and filter emboli out of blood flowing through a vessel in which the filter is deployed. Treatment devices such as a balloon catheter or a stent balloon catheter disclosed in Irish Application No. 97 0789 are inserted into a vessel to treat a portion of the vessel, and are advanced along the guidewire to a position proximal of the filter element, as described in Irish Application No. 97 0789. The inner lumen of the polyimide tube filter support shown in Exhibit 90 has a diameter of 0.0145", and the proximal region of the guidewire has an outer diameter of 0.013". Exhibit 90 thus confirms that rotation or distal translation of a guide wire relative to the filter element does not displace the filter element. The guidewire can be translated through the filter polyimide tube support without displacing the filter element. The guidewire can also be rotated in the filter polyimide tube support without

displacing the filter element.

The filter system shown in Exhibit 90 is used in the methods described in Irish Application 97 0789, in which the guidewire is first steered across the lesion, through the filter support, and the filter is then threaded over the inserted guidewire and deployed in the vessel (page 12, lines 3-11). The filter is attached to a shaft that can run over the prior crossing guidewire (page 12, lines 11-13), and rotation or distal translation of the guidewire relative to the filter support shaft thus does not displace the filter element.

46. Prior to March 5, 1998, I understood that the filter system shown in Exhibit 90 was designed by the inventors to be used in the methods described in Irish Application 97 0789, in which the guidewire is first steered across the lesion, through the filter support, and the filter is then threaded over the inserted guidewire and deployed in the vessel. The filter is attached to a shaft that can run over the prior crossing guidewire, and rotation or distal translation of the guidewire relative to the filter support shaft does not displace the filter element. I understood that treatment devices such as a balloon catheter or a stent balloon catheter are inserted into a vessel to treat a portion of the vessel, and are advanced along the guidewire to a position proximal of the expanded filter element. I understood that one significant advantage of the filter system shown in Exhibit 90 was that that guidewire could be manipulated independently relative to the filter element, and could be extended through the filter element and rotated without displacing the filter element. The inventors disclosed to me that independent translation and rotation of the guidewire relative to the filter element would have significant advantages in steering the guidewire into position in a vessel,

past a stenosis partially closing the vessel, prior to inserting and deploying the filter in the vessel.

47. With regard to Count 2, prior to March 5, 1998, the inventors disclosed to me the following aspects of their invention which are described in Irish Application No. 97 0789:

Disclosure of Irish Application No. 97 0789
A filter element provides a pathway for blood and has means for capturing and retaining undesired embolic material released during a surgical procedure (page 11, lines 19-24). The device is used in an over the wire transcatheter configuration, in which the clinician will cross the lesion with a steerable guidewire (page 12, lines 3-5). The device consists of a filter attached to a shaft that can run over the primary crossing guidewire (page 12, lines 11-13); the shaft is disposed for translation on the guide wire proximal of the distal end of the guidewire, for example, substrate shaft 33 in Figs. 11-15 and 18 which is threaded over a guidewire (page 16, lines 6-8). Fig. 18 discloses a filter element having a plurality of Nitinol shape-memory struts, formed to remember an open shape, having a balloon filter affixed to the support (page 18, lines 9-14); the membrane filter fabric may be bonded to the supporting spoke framework (page 15, lines 25-31) or attached over the Nitinol frame (page 17, lines 6-7). The clinician will cross the lesion with a steerable guidewire, and the filter is then threaded over the guidewire and placed distal to the site of the lesion being treated (page 12, lines 4-8). The self-expanding filter of Fig. 18 is deployed in the vessel and will capture emboli (page 12, lines 8-11); the expanded filter element will occlude the vessel except for the path or paths provided through the filter (page 12, lines 21-24).

The deployed filter will capture emboli that are generated or dislodged during balloon inflation and stent placement, which are treatment devices advanced along the guide wire to a position proximal to the location of the filter (page 12, lines 8-11; page 19, lines 10-17; claims 23, 24). Because the shaft or hollow support element (page 12, lines 14-18) on which the filter is mounted is not fixed to the guidewire (page 12, lines 11-13), rotation or distal translation of the guidewire relative to the filter element does not displace the filter element. The guidewire moves independently from the filter: it is first steered across the lesion, and the filter is then threaded over the inserted guidewire and deployed in the vessel (page 12, lines 3-11). During retrieval, the filter can be withdrawn either with the guidewire or over it (page 16, lines 23-25). The filter is attached to a shaft that can run over the prior crossing guidewire (page 12, lines 11-13), and rotation or distal translation of the guidewire relative to the filter support shaft thus does not displace the filter element.

48. With regard to Count 2, prior to March 5, 1998, the inventors disclosed to me the embodiment described in Exhibit 1, and I appreciated at that time that Exhibit 1 discloses the following aspects of their invention:

Neuroguard Details and Dims.
The CHRONOFLEX balloon filter is used in the method disclosed in Irish Application No. 97 0789, as shown in Fig. 18. Guidewire having a maximum shaft outer diameter (O.D.) of 0.014″. The balloon filter is disposed on a polyimide tube having an inner diameter (I.D.) of 0.0145″, and is thus disposed for translation on the guide wire proximal to the distal end of the guide wire. Self-expanding Nitinol shape-memory struts support the filter sac, shown with large proximal holes and small distal holes, in expanded configuration. Exhibit 1 illustrates the filter polyimide tube support and guidewire extending through a delivery catheter that is transluminally inserted into a vessel, as described in Irish Application No. 97 0789. The self-expanding CHRONOFLEX filter is shown in deployed configuration, as described in Irish Application No. 97 0789, to engage a wall of the vessel and filter emboli out of blood flowing through a vessel in which the filter is deployed. Treatment devices such as a balloon catheter or a stent balloon catheter are treatment devices which are inserted into a vessel to treat a portion of the vessel, and in the device shown in Exhibit 1, they are advanced along the guidewire to a position proximal of the filter element, as described in Irish Application No. 97 0789. Because Exhibit 1 describes the inner lumen of the polyimide tube as having a diameter of 0.0145″, and the guidewire has a maximum shaft outer diameter of 0.014″, Exhibit 1 discloses that rotation or distal translation of the guide wire relative to the filter element does not displace the filter element.

49. As stated above, prior to March 5, 1998, the inventors disclosed to me their conception of a stepped guidewire, having a distal stop which restricted distal translation of the filter element on the guidewire.

50. As shown in Exhibit 1, the polyimide tube on which the balloon filter is mounted was designed to rotate and translate on a guidewire, because the guidewire had a smaller diameter (0.014″) than the inner lumen of the polyimide tube (0.0145″).

51. Prior to March 5, 1998, the inventors disclosed to me that a small clearance between the guidewire and the polyimide tube caused undesirable friction between the guidewire and the tube.

52. Prior to March 5, 1998, I received an email from Padraig Maher on the subject "Review of Polyimide tubing functionality," which was sent to Eamon Brady, Fergal Farrell, me, Mairsil Claffey; Susan Eighan, Ruth Houlihan, and Paul Gilson, and is attached as Exhibit 2.

53. As Padraig Maher disclosed in Exhibit 2, the inventors informed me that that the lumen was too tight for the guidewire over the 3 meter length of the polyimide tube. The inventors also appreciated that it would be desirable to devise a mechanism for locking the polyimide tubing to the guide wire.

54. In the embodiment disclosed in Exhibit 1, the Chronoflex embolic filter is attached to a long polyimide tube, which has a lumen that is sized to permit rotation and translation of the filter element (*i.e.*, the polyimide tube support and the Chronoflex filter mounted thereon) on the guidewire.

55. As shown by Exhibit 2, the inventors disclosed to me that due to the long length of the polyimide tube, which must bend in order to conform to the path followed by the filter element in the arteries, there was friction between the 0.014″ guidewire and the lumen of the polyimide tube, which was 0.145″.

56. Prior to March 5, 1998, the inventors also disclosed to me that there was friction between the exterior of the long polyimide tube and the lumen of the retrieval catheter, which significantly increased the force required to withdraw the embolic filter into the withdrawal catheter, by pulling on the polyimide tube.

57. Prior to March 5, 1998, the inventors informed me that they considered that the stepped 0.013″/0.016″ guidewire configuration described above, which provides a distal stop, would permit the transfer of some of the withdrawal load from the polyimide tube to the guidewire, by retracting the guidewire in a proximal direction to cause the thicker distal guidewire tip portion to abut against the polyimide tube support of the filter element, thus reducing the load on the filter element during withdrawal.

58. Prior to March 5, 1998, the inventors also informed me that they considered that this stepped guidewire configuration would permit the guidewire to be used to withdraw the expanded filter into a retrieval catheter, by retracting the thicker distal stop portion of the guidewire to abut the end of the polyimide tube filter support, and by pulling the guide wire proximally to retract the filter element into a retrieval catheter.

59. The inventors disclosed to me that retracting the guide wire in a proximal direction causes the distal stop to abut against the filter element, when the guidewire is pulled to retract the filter element into a retrieval catheter, and disclosed this advantage to me prior to March 5, 1998.

60. With regard to Count 2, prior to March 5, 1998, I understood that the prototype NeuroShield Mark 1 filter system as shown in Exhibit 90, discussed above, incorporated each of the following aspects of the invention:

NeuroShield Mark 1 Prototype (Exhibit 90)
The filter system is used in the method disclosed in Irish Application No. 97 0789, where a representative filter is shown, *e.g.*, in Fig. 18. The balloon filter shown in Exhibit 90 is mounted on a polyimide tube support having an inner diameter of 0.0145", and the filter is disposed for translation on a guide wire proximal of the distal stop. The polyimide tube support prevents the filter from translating distal of the guidewire stop. The balloon filter shown in Exhibit 90 has a number of self-expanding Nitinol shape-memory struts supporting the expanded filter sac, which is attached to the Nitinol support. The balloon filter is shown in Exhibit 90, in its deployed configuration, as described in Irish Application No. 97 0789, such that it would engage a wall of the vessel and filter emboli out of blood flowing through a vessel in which the filter is deployed. Treatment devices such as a balloon catheter or a stent balloon catheter are treatment devices which are inserted into a vessel to treat a portion of the vessel, and in the device shown in Exhibit 1, they are advanced along the guidewire to a position proximal of the filter element, as described in Irish Application No. 97 0789. The inner lumen of the polyimide tube filter support shown in Exhibit 90, has a diameter of 0.0145", and a proximal region of the guidewire has an outer diameter of 0.013". Exhibit 90 thus confirms that rotation or distal translation of the guide wire relative to the filter element does not displace the filter element. The guidewire can be translated through the filter polyimide tube support without displacing the filter element. The guidewire can also be rotated in the filter polyimide tube support without displacing the filter element. As shown in Exhibit 90, in order to retrieve the filter, the guidewire is retracted to cause the distal stop to abut against the filter element. The prototype filter system included a wire lock device, which is used to hold the guidewire in place while the retrieval catheter is pushed over the filter, with the distal stop abutting against the filter element

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Declaration of John O'Shaughnessy

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 16 Dec 05

John O'Shaughnessy